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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,704	12/04/2003	Volkmar Guenzler-Pukall	FP0602.1 US	5297

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FIBROGEN, INC.
409 Illinois Street
San Francisco, CA 94158

EXAMINER	
TELLER, ROY R	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
09/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,704	GUENZLER-PUKALL ET AL.	
	Examiner	Art Unit	
	ROY TELLER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment, received 6/1/09, in which applicant amended claims 43-47 and added new claims 49-56. [Note: an offer of allowance with an examiner's amendment was declined by applicant's representative on 9/14/09.]

Claims 43-56 are under examination.

Response to Amendments/Arguments

Applicant's arguments and amendments filed 6/1/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating diabetes in a diabetic subject, the method comprising administering to the subject an effective amount of a heterocyclic carbonyl glycine compound which inhibits HIF hydroxylase, wherein the compound selected from the group consisiting of is [(7-chloro-3-hydroxy-quinoline-2-carbonyl)-amino]-acetic acid; [(1-chloro-4-hydroxy-isoquinoline-3-carbonyl)-amino]acetic acid; [(4-hydroxy-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid; 4-oxo-1,4-dihydro-[1,10]phenanthroline-3-carboxylic acid; [(1-chloro-4-hydroxy-7-methoxy-isoquinoline-3-carbonyl)-amino]-acetic acid; [(3-hydroxy-6-

isopropoxy-quinoline-2-carbonyl)-amino]acetic acid; [(3-hydroxy-pyridine-2-carbonyl)-amino]acetic acid; or [(7-benzyloxy-1-chloro-4-hydroxy-isoquinoline-3-carbonyl)-amino]-acetic acid methyl ester, thereby treating the diabetes, does not reasonably provide enablement for a method for treating diabetes in a diabetic subject, the method comprising administering to the subject an effective amount of a heterocyclic carbonyl glycine compound which inhibits HIF hydroxylase, thereby treating the diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to a method comprising administering to the subject an effective amount of a heterocyclic carbonyl glycine compound which inhibits HIF hydroxylase, thereby treating the diabetes.

The breadth of the claims is excessive with regard to claiming a method comprising

administering to the subject an effective amount of a heterocyclic carbonyl glycine compound which inhibits HIF hydroxylase, thereby treating the diabetes. Applicant has only provided guidance for the use of a heterocyclic carbonyl glycine compound which inhibits HIF hydroxylase, wherein the compound selected from the group consisiting of is [(7-chloro-3-hydroxy-quinoline-2-carbonyl)-amino]-acetic acid; [(1-chloro-4-hydroxy-isoquinoline-3-carbonyl)-amino]acetic acid; [(4-hydroxy-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid; 4-oxo-1,4-dihydro-[1,10]phenanthroline-3-carboxylic acid; [(1-chloro-4-hydroxy-7-methoxy-isoquinoline-3-carbonyl)-amino]-acetic acid; [(3-hydroxy-6-isopropoxy-quinoline-2-carbonyl)-amino]acetic acid; [(3-hydroxy-pyridine-2-carbonyl)-amino]acetic acid; or [(7-benzyloxy-1-chloro-4-hydroxy-isoquinoline-3-carbonyl)-amino]-acetic acid methyl ester,thereby treating the diabetes.

Applicant have provided no guidance of any other ingredient which act as a heterocyclic carbonyl glycine compound which inhibits a hypoxia inducible factor (HIF) hydroxylase. In absence of evidence to the contrary, it would not be expected that any and all ingredients would act as a HIF hydroxylase inhibitor, other than a heterocyclic carbonyl glycine compound which inhibits HIF hydroxylase. Furthermore, it would not be predictable to the artisan which ingredient that inhibits HIF hydroxylase would work in the present invention, nor would it be predictable to the artisan which pathologies could be treated with these ingredients that act as a inhibitory substance.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to

practice the invention as claimed.

Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success, other than the use of a heterocyclic carbonyl glycine compound which inhibits HIF hydroxylase, wherein the compound selected from the group consisiting of is [(7-chloro-3-hydroxy-quinoline-2-carbonyl)-amino]-acetic acid; [(1-chloro-4-hydroxy-isoquinoline-3-carbonyl)-amino]acetic acid; [(4-hydroxy-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid; 4-oxo-1,4-dihydro-[1,10]phenanthroline-3-carboxylic acid; [(1-chloro-4-hydroxy-7-methoxy-isoquinoline-3-carbonyl)-amino]-acetic acid; [(3-hydroxy-6-isopropoxy-quinoline-2-carbonyl)-amino]acetic acid; [(3-hydroxy-pyridine-2-carbonyl)-amino]acetic acid; or [(7-benzyloxy-1-chloro-4-hydroxy-isoquinoline-3-carbonyl)-amino]-acetic acid methyl ester, thereby treating the diabetes to provide the functional effects instantly claimed, as shown in the instant specification, page 37, paragraph 139.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, first paragraph for the reasons set forth above.

Conclusion

All claims are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
9/21/09

/Christopher R. Tate/
Primary Examiner, Art Unit 1655